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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,692	03/11/2004	Mark W. Becker	249.P1C2	6194

25000 7590 01/24/2006

GILEAD SCIENCES INC
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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,692

Applicant(s)

BECKER ET AL.

Examiner

Louise N. Leary

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34,37,42,43,46 and 47 is/are allowed.
- 6) ☒ Claim(s) 35,36,38-41,44 and 45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. Claims 34-47 are pending in this application.

Claims 1-33 have been canceled per applicant's request in the Preliminary Amendment filed September 17, 2004.

2. The provisional rejection of claim 36 under 35 USC 101 as claiming the same invention as that of claim 23 of copending Application No. 10/354207 has been maintained for reasons of record.

3. The rejection of claims 36-41 under 35 USC 112, second paragraph, is moot in view of the claim amendments filed October 18, 2005.

4. The provisional nonstatutory double patenting rejections under the judicially created doctrine of obviousness-type double patenting listed below have been maintained for reasons of record.

(A) The provisional obviousness-type double patenting rejection of claim 35 as being unpatentable over claim 1 of copending Application No. 11/031228 has been maintained for reasons of record.

(B) The provisional obviousness-type double patenting rejection of claim 35 as being unpatentable over claim 1 of copending Application No. 11/031250 has been maintained for reasons of record.

(C). The provisional obviousness-type double patenting rejection of claim 35 as being unpatentable over claim 1 of copending Application No. 11/031251 has been maintained for reasons of record.

(D). The provisional obviousness-type double patenting rejection of claim 35 as being unpatentable over claim 1 of copending Application No. 11/031252 has been maintained for reasons of record.

5. NEW GROUNDS OF OBJECTION:

Claims 38-41 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

(II). NEW GROUNDS OF REJECTION

(i). Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031228.

(ii). Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031250.

(iii). Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031251.

(iv). Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031252.

6. Applicant's arguments filed October 20, 2005 have been fully considered but they are not persuasive.

(I). At page 15 of the "Remarks", applicants have asserted "[Claim 36 was provisionally rejected on the grounds of double patenting over claim 23 of copending application 10/354207. This rejection is believed to be without merit because claim 36 recites that the subject diastereomer is enriched. Claims 23 of the '207 application (copy attached as exhibit 1) is silent on the question of purity and therefore is directed to the given enantiomer as well as the racemate of which is a part. Therefore it is not directed to the same invention as claim 36.]"

It is noted that the provisional rejection of claim 36 on the grounds of double patenting over claim 23 of copending application 10/354207 has merit. This rejection has merit because both inventions claim identical chemical compounds represented by the "structure (6)". Specifically, both inventions claim identical "salts and solvates" chemical compounds represented by the "structure (6)" formula claimed. Both

inventions are silent on the question of substantial purity. Neither invention excludes the identical salts and solvates compounds represented by the "structure (6)" formula claimed.

Therefore, both inventions claim identical chemical compounds. Alternatively, both inventions are directed to the same invention which renders the provisional rejection of claim 36 on the grounds of double patenting over claim 23 of copending application 10/354207 proper.

(II). Applicants have stated "[Claim 35 was provisionally rejected on the ground of obviousness-type double patenting over copending application no. 11/031228, 11/031250, 11/031251 and 11/031252. Since these rejections are provisional, this application should now be in condition for allowance.]"

However, the provisional rejections of claim 35 has been maintained because to date no terminal disclaimer or claim amendment has been filed to overcome these rejections.

The provisional rejections have been maintained for the reasons given below.

(A) Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031228. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim compounds that can be identical. Specifically, the compound structure identified as (5a) in the instant

application is identical to the compound structure identified as (1a) in copending Application No. 11/031228. Likewise, the compound structure identified as (5b) in the instant application is identical to the compound structure identified as (1b) in copending Application No. 11/031228. It is noted that the selection of varying percent by weight of compounds represented by "(5b)" does not change the actual chemical structure. Further, varying and selecting different percent by weight of diastereomer "(5b)" was deemed within the purview of skilled artisans at the time this invention was made. Hence, both inventions selectively claim the same compounds. Thus, there is substantial overlap of the subject matter claimed in both inventions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(B) Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031250. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim compounds that can be identical. Specifically, the compound structure identified as (5a) in the instant application is identical to the compound structure identified as (1a) in copending Application No. 11/031250. Likewise, the compound structure identified as (5b) in the instant application is identical to the compound structure identified as (1b) in copending Application No. 11/031250. It is noted that the selection of varying percent by weight of compounds represented by "(5b)" does not change the actual chemical structure.

Further, varying and selecting different percent by weight of diastereomer "(5b)" was deemed within the purview of skilled artisans at the time this invention was made. Hence, both inventions selectively claim the same compounds. Thus, there is substantial overlap of the subject matter claimed in both inventions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(C) Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031251. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim compounds that can be identical. Specifically, the compound structure identified as (5a) in the instant application is identical to the compound structure identified as (1a) in copending Application No. 11/031251. Likewise, the compound structure identified as (5b) in the instant application is identical to the compound structure identified as (1b) in copending Application No. 11/031251. It is noted that the selection of varying percent by weight of compounds represented by "(5b)" does not change the actual chemical structure. Further, varying and selecting different percent by weight of diastereomer "(5b)" was deemed within the purview of skilled artisans at the time this invention was made. Hence, both inventions selectively claim the same compounds. Thus, there is substantial overlap of the subject matter claimed in both inventions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(D) Claims 35 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031252. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim compounds that can be identical. Specifically, the compound structure identified as (5a) in the instant application is identical to the compound structure identified as (1a) in copending Application No. 11/031252. Likewise, the compound structure identified as (5b) in the instant application is identical to the compound structure identified as (1b) in copending Application No. 11/031252. It is noted that the selection of varying percent by weight of compounds represented by “(5b)” does not change the actual chemical structure. Further, varying and selecting different percent by weight of diastereomer “(5b)” was deemed within the purview of skilled artisans at the time this invention was made. Hence, both inventions selectively claim the same compounds. Thus, there is substantial overlap of the subject matter claimed in both inventions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Therefore, for the reasons given above the rejections of the claims 35, 36 and 44-45 have been maintained.

7. Claims 38-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 34, 37, 42-43 and 46-47 are allowable over the prior art of record.


9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY
PRIMARY EXAMINER

December 14, 2005